Early versus late tracheostomy in patients who require prolonged mechanical ventilation

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Early versus late tracheostomy in patients who require prolonged mechanical ventilation. For the purpose of the study, early tracheostomy was defined as tracheostomy performed by day 10 after the initiation of mechanical ventilation and late tracheostomy as tracheostomy performed after day 10 of mechanical ventilation.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients over 17 years of age undergoing tracheostomy while in the medical intensive care unit (ICU). Patients were excluded if they had been transferred from other hospitals where they had already started receiving mechanical ventilation.

Setting
Secondary care, namely the Barnes-Jewish Hospital, St Louis, Mo. The economic study was conducted in the USA.

Dates to which data relate
Effectiveness and cost data were collected between August 1997 and December 1998. The price year was not reported.

Source of effectiveness data
The evidence for final outcomes was derived from a single study.

Link between effectiveness and cost data
Costing was undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
90 consecutive patients who underwent tracheostomy in the ICU were considered. 53 patients had early tracheostomy (performed by day 10 of mechanical ventilation) and 37 had late tracheostomy. The mean age (+/- SD) of patients in the study cohort was 60.1 (+/- 17.5) years, with 38.9% men and 61.1% women. The sample size was estimated to provide 80% power to detect a 5-day difference in the duration of mechanical ventilation between the two study groups.

Study design
This was a prospective single-centre observational study. Patients were followed-up until they were discharged from hospital, were transferred to a long-term care facility, or died.

**Analysis of effectiveness**
The analysis of effectiveness was based on intention to treat. The main health outcome used in the analysis was the duration of mechanical ventilation and the secondary outcome measures included length of stay in the ICU and hospital, hospital mortality and the rates of reintubation and nosocomial pneumonia. The two study groups were similar in terms of age, with 26 male patients in the early tracheostomy group compared to only 6 males in the late tracheostomy group.

**Effectiveness results**
The mean duration of medical ventilation was 28.3 days (SD 28.2) in the early group and 34.3 (SD 17.8) days in the late group. The mean length of stay was 15.6 (SD 9.3) days in early group versus 29.3 (SD 15.4) for the late group in the intensive care unit. Mean length of stay in the hospital was 44.8 (SD 30.3) days for the early group versus 49.6 (SD 22.3) days for the late group. Hospital mortality was 15 (28.3%) in the early group versus 14 (37.8%) in the late group. There were 16 cases of nosocomial pneumonia (30.2%) in the early group and 16 (43.2%) in the late group. 15 of the early group were reintubated (28.3%) compared to 17 (45.9%) in the late group. Logistic regression analysis indicated that male sex (adjusted odds ratio 3.84, 95% CI: 2.32 - 6.34, p=0.007) and greater PaO2/FIO2 ratio (adjusted odds ratio 1.01, 95% CI: 1 - 1.01; p=0.03) were the two baseline variables independently associated with the performance of early tracheostomy.

**Clinical conclusions**
Early tracheostomy is a safe procedure in patients who require prolonged mechanical ventilation.

**Modelling**
A logistic regression analysis was performed using a SAS/STAT package. A stepwise approach was used for entering new terms into the model, with 0.05 as the limit for their acceptance or removal.

**Measure of benefits used in the economic analysis**
The authors did not provide a summary measure of benefits and, as such, a cost-consequences analysis was performed, and the reader is referred to the effectiveness results reported above.

**Direct costs**
Direct costs were considered, namely hospitalisation costs. Professional fees for the services of physicians, including consultants, were not included in these calculations. Quantities and cost were not presented separately and costs were not discounted due to the short duration of the study. The business office at the Barnes-Jewish hospital provided cost data. The price year was not reported.

**Statistical analysis of costs**
Statistical analysis of costs was performed using the Wilcoxon rank-sum test.

**Indirect Costs**
Indirect costs were not considered.

**Currency**
US dollars ($).
Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
As no summary benefit measure was provided, the reader is referred to the effectiveness results reported above.

Cost results
The total cost of hospitalisation was significantly lower in the early tracheostomy group (mean +/-SD $86,198 +/- 53,570) than in the late-tracheostomy group (mean +/- SD $124,649 +/- 54,282), (p=0.001).

Synthesis of costs and benefits
A synthesis of costs and benefits was not available due to the cost-consequences approach adopted.

Authors’ conclusions
Early tracheostomy is associated with shorter mechanical ventilation, shorter hospital stay and lower costs than late tracheostomy among patients in the ICU. Patients in the early tracheostomy group were significantly more likely to be male, to have greater PaO2/FIO2 ratios and to have a diagnosis of ARDS than patients in the late tracheostomy group. Prospective clinical trials are necessary to determine the optimal timing of tracheostomy in this setting.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator, late tracheostomy, was clear, because this mechanical ventilation procedure was widely used in the authors’ setting. You, as a database user, should consider if the same applies to your own setting.

Validity of estimate of effectiveness:

The analysis was based on a prospective single-centre observational study, which was appropriate for the study question. The study sample was representative of the study population and power calculations were used to determine the sample size. Patients in the early tracheostomy group were significantly more likely to be male, to have greater PaO2/FIO2 ratios and to have a diagnosis of ARDS than patients in the late tracheostomy group. Appropriate statistical analyses were undertaken to take account of potential biases and confounding variables.

Validity of estimate of health benefit:

The authors did not derive a measure of health benefit and the analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
Insufficient details of cost estimation were given and it was, therefore hard to judge whether important cost items had been omitted from the analysis. The reason for the reduced cost of hospitalisation in patients who had early tracheostomy is unclear. The difference in duration of mechanical ventilation may have accounted for the difference in costs between the two study groups.

Other issues
In terms of the generalisability of results, the authors noted that:

the study was not a randomised trial;
the study was limited to a single ICU in a single institution and practices there may not represent practices in other settings;

day 10 was selected as the cut-off day on the basis of the mean timing of tracheostomy in the authors’ institution; and

they were not able to specify which elements of the total hospital costs were greater for the late-tracheostomy group than for the early one.

The authors made appropriate and detailed comparisons with the results of other similar studies.

Implications of the study
Prospective clinical trials are necessary to determine the optimal timing of tracheostomy. Inadvertent extubation is another important variable when the outcomes of early versus late tracheostomy are being considered and this variable should be considered in future studies.

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